

AUG - 5 1996

Mr. Charles J. Raubicheck  
Piper & Marbury  
1251 Avenue of the Americas  
New York, New York 10020-1104

Dear Mr. Raubicheck:

This is in response to your letter of July 8, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that your client, Cartilage Technologies, Inc. of Elmsford, New York, is making the following statements in the labeling of their products:

**"Photo-EST™"**

Soya isoflavones such as genistein are among the most versatile and powerful nutraceuticals known to modern medical science. Soya isoflavones have been shown in modern scientific research to have powerful anti-oxidant activity and antiangiogenic activity, and they are nature's estrogens to avert menopausal symptoms.

**"PEPOGEST™"**

Smooths out gastrointestinal function.

Peppermint and fennel oils have a natural and spasmodic effect on the gastrointestinal tract. These oils have been used for many years in the treatment of symptoms such as abdominal distress, colic and troublesome manifestations of irritability of the bowel. You can now enjoy the proven benefits of these oils in smoothing out gut function by the use of PEPOGEST™. PEPOGEST™ is a delayed release, physician formulated, natural remedy for colic, gas and irritable intestines. In addition, PEPOGEST™ can be used to make a colostomy more acceptable.

Peppermint and fennel oils may relax the intestines and assist in the relief of distress, colic and flatulence of the gut. These essential oils are carminative with local effects on the bowels. Improves the acceptance of a colostomy.

We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that your client is making for these products suggest that they are intended for one of these purposes, in that: (1) 'Phyto-EST™' claims to avert menopausal symptoms and (2) "PEPOGEST™" claims that [T]hese oils have been used for many years in the treatment of symptoms such as abdominal distress, colic and troublesome manifestations of irritability of the bowel; "PEPOGEST™" is a natural remedy for colic, gas and irritable intestines; [P]eppermint and fennel oils may relax the intestines and assist in

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**the relief of distress, colic and flatulence of the gut;" and it "[I]mproves the acceptance of a colostomy." These claims on the label or in the labeling of these products evidence that they are intended to prevent, cure, treat, or mitigate disease and that the products are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.**

**Please contact us if we may be of further assistance.**

**Sincerely yours,**

**James Tanner, Ph.D.  
Acting Director,  
Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition**

**Copies:**

**FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300**

**FDA, New York District Office, Office of Compliance, HFR-SW1**

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,  
HFC-200**